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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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05/25/2005

Sergei Braun

29948

4946

67801

7590

10/16/2008

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EXAMINER

MESH, GENNADIY

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/536,467	BRAUN, SERGEI	
	<b>Examiner</b>	<b>Art Unit</b>	
	GENNADIY MESH	1796	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 132-139 and 141-143 is/are pending in the application.
- 4a) Of the above claim(s) 114-131 and 145 - 152 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 132-139 and 141-143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's Amendment filed on June 23, 2008 is acknowledged.

Applicant cancelled Claims 140 and 144. Claims 132 - 139 and 141 - 143 are active.

Rejection is maintained as it was set forth in previous Office action mailed on February 21, 2008.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 132 – 139 and 141 - 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al.( US Re. 30,170) in view of Gouesnard “Reactivite du nitrite de sodium. V. Action sur les amino-acides, peptides et proteines” *BULLETIN DE LA SOCIETE CHIMIQUE DE FRANCE* 1989 N° 1 – cited by Applicant.

Goodman discloses hydrolysable copolymers of natural amino acids and hydroxyacids obtain by incorporation of alpha ( or beta or gamma) hydroxyacids residue in peptide backbone ( see abstract and column 1, lines 12-18), wherein amino acid ( see radicals B claimed by Applicant) and hydroxyacid linked by ester bond ( see Goodman , general formula on bottom of column 1 and in the top of column 2) – same as it require by A-B bond of radicals A and B in Claims 132 - 139 and 141 - 143.

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According to Goodman ( see column4,lines 15-25) presence of ester bond "to endow it ( polymers) with the desirable hydrolysable properties".

Note, that residue of natural amino acid in general formula provided by Goodman ( see general formula on bottom of column 1 and in the top of column 2) reads on radical B.

Goodman is silent regarding use of radicals A as hydroxy amino acids.

However, Gouesnard teach that hydroxy amino acids can be obtain by treating proteins with sodium nitrite ( see Scheme 1, page 89).

Therefore, it would be obvious to one of ordinary skill in the art to use hydroxy amino acids obtained per teaching of Gouesnard instead of hydroxyacids in order to prepare hydrolysable polyesters as it disclosed by Goodman with reasonable expectation of success, until unexpected results to the contrary can be shown by Applicant.

### ***Response to Arguments***

2. Applicant presented arguments against anticipatory rejection under 35 U.S.C. 102(b) as being anticipated by Goodman (in view of Gouesnard). Note, that this rejection have not been made in Office action mailed on February 21, 2008.

At same time Applicant presented arguments against rejection based on U.S.C. 35 103(a) as being unpatentable over Goodman et al.( US Re. 30,170) in view of Gouesnard. This rejection **was made in previous Office action**. Therefore, applicant's arguments related to this rejection are considered and answered in next paragraph.

3. Applicant's arguments filed June 23, 2008 have been fully considered but they are not persuasive.

Applicant's arguments related to Claims 132 - 139 and 141 - 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US Re. 30,170) in view of Gouesnard based on following:

i) Applicant stated that " As would be apparent to one skilled in the art, a hydroxy amino acid is liable to form an amide bond (via the amino group thereof) instead of the ester bond desired according to the teachings of Goodman et al. The teachings of Goodman et al. can therefore be achieved with a hydroxy amino acid only if the amino group in the hydroxy amino acid **does not** react to form an amide bond, and the hydroxy group therein does react to form an ester bond " and for this reason, Therefore, modification of the method disclosed by Goodman by replacing hydroxyacids with hydroxyl amino acids per teaching of Gouesnard " would create technical of having to prevent amide bond formation, in order to facilitate the desired ester bond formation" because Goodman " does not even remotely suggest how such a selective reactivity can be achieved" - see Arguments page 23.

This argument was not found persuasive for several reasons:

It is clear, that **all possible reactions will occur** ( rate of reaction , of course , will be different), including reaction which will lead to ester bond formation. Thus, some quantity of ester bond always will be present in polymeric structure.

Goodman recognized that, not only polymers, wherein ester bond incorporated to backbone ( see general formula on bottom of column 1 and in the top of column 2 ), but also several different polymers will be produced as a result of the method ( see column 3, lines 19 - 43), including soluble and **insoluble in benzene**, which indicated that polymer has **peptide structure with no presence of ester bond in backbone**.

Goodman, also recognized that different reaction condition, specific solvent and specific catalyst will facilitate one type of reaction compare to other( see column 3, lines 44 - 51 and 57 - 68 and column 4, lines 1-15) and pointing out that only **relatively small amount of ester bonds has to be incorporated to backbone of polymer in order to polymer become hydrolysable** ( see column 4, lines 15 - 24) and providing method of isolating polymers with ester bonds based on difference in solubility of hydrolysable polymers ( see Example II).

Therefore, applicant's arguments were found unpersuasive.

ii) Applicant also stated that " Goodman teaches a linear polymer having hydrolysable ester bonds... but as " well known in the art , the introduction of branching and/ or cross-linking of polymer molecules would be expected to make the polymer less hydrolysable" and for this reason Goodman is not using amino acids with reactive groups.

It is noted that Applicant did not present any data to support this statement.

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It is reasonable to believe that at certain degree of crosslinking, when polymer is still **soluble**, hydrolysability of the polymer will not significantly change by presence of crosslinking, but will be determine by quantity of hydrolysable bonds in polymer backbone, until Applicant can present data to the contrary.

Therefore, all applicant's arguments were found unpersuasive.

### ***Conclusion***

#### **THIS ACTION IS NOT MADE FINAL.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gennadiy Mesh  
Examiner  
Art Unit 1796

/GM/

/Vasu Jagannathan/  
Supervisory Patent Examiner, Art Unit 1796